UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte D. WADE WALKE,
BRIAN MATHUR, C. ALEXANDER TURNER JR.,
CARL JOHAN FRIDDLE, and BRENDA GERHARDT

Appeal No. 2005-1920
Application No. 09/918,359

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 5-9, all of the claims remaining. Claim 1 is representative and reads as follows:

1. An isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:7.

The examiner relies on the following references:

Bork, "Go hunting in sequence databases but watch out for the traps," TIG, Vol. 12, No. 10, pp. 425-427 (1996)

Doerks et al., "Protein annotation: detective work for function prediction," TIG, Vol. 14, No. 6, pp. 248-249 (1998)

Brenner, "Errors in genome annotation," TIG, Vol. 15, No. 4, pp. 132-133 (1999)

Voet et al., BIOCHEMISTRY, John Wiley & Sons, pp. 126-128 and 228-234 (1990)

Adams et al., EST180740 Jurkat T-cells V Homo sapiens cDNA 5' end, mRNA sequence. Accession No. AA309878 (1997)

Claims 1 and 5-9 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility.

We affirm.

Background

The specification discloses polynucleotides encoding human proteins (referred to generically as a "novel human proteins" or NHPs) that "share structural similarity with mammalian ion channel proteins, and particularly voltage-gated potassium channel proteins." Page 2. One of the disclosed polynucleotides encodes a polypeptide of 485 amino acids (with the amino acid sequence shown in SEQ ID NO:7). Page 2, lines 9-12. The specification does not further characterize the polypeptide of SEQ ID NO:7 or its encoding polynucleotide, but notes that "[i]on channel proteins are integral membrane proteins that mediate or facilitate the passage of materials across the lipid bilayer." Page 1.

The specification does not disclose what role the protein of SEQ ID NO:7 plays in any physiological process, but contemplates "processes for identifying compounds that modulate, i.e., act as agonists or antagonists, of NHP expression and/or NHP activity .

. . . Such compounds can be used as therapeutic agents for the treatment of a wide variety of symptoms associated with biological disorders or imbalances." Page 3.

The specification states that "suitably labeled NHP nucleotide probes can be used to screen a human genomic library using appropriately stringent conditions or by PCR. The identification and characterization of human genomic clones is helpful for identifying polymorphisms . . . , determining the genomic structure of a given locus/allele, and designing diagnostic tests." Page 10.

The NHP protein is disclosed to be useful "in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders and disease. Given the similarity information and expression data, the described NHPs can be targeted . . . in order to treat disease, or to therapeutically augment the efficacy of, for example, chemotherapeutic agents used in the treatment of breast and prostate cancer." Pages 18-19.

Finally, the specification discloses that several polymorphic positions were identified in SEQ ID NO:6. Pages 15-16.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.[1] The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the

[1] The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner's

burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373. "Consequently, because Fisher

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Answer, page 6. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, the examiner found the specification's disclosure to be inadequate because

> [t]he instant claims are drawn to a nucleic acid encoding a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as NHP, the instant invention is incomplete. In the absence of knowledge of the natural substrate or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit its activity is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real world" use for NHP then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

Examiner's Answer, page 5.

Appellants argue that the claimed nucleic acids encode a protein with a high degree of similarity to a calcium channel protein, and therefore those skilled in the art would accept the specification's statement that the encoded protein is an ion channel.

Appeal Brief, page 12. "Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101." Id.

We do not agree that the characterization of the claimed nucleic acids as encoding an ion channel protein is sufficient to establish their utility.[2] The specification states only that "[i]on channel proteins are integral membrane proteins that mediate or facilitate the passage of materials across the lipid bilayer." Page 1. The specification provides no information regarding what ion is transferred into or out of cells by the protein of SEQ ID NO:7, or what biological functions or activities involve ion transfer mediated by the protein of SEQ ID NO:7.[3]

Thus, the record does not support Appellants' position that the characterization of a polypeptide as an ion channel protein would have suggested a specific biological function, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. In the terms used by the Fisher court, such a characterization does not provide a substantial utility because it does not show that the claimed invention is useful as disclosed in its current form, only that it may be useful at some future date after further research: the specification does not disclose a significant and

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[2] The examiner argues that those skilled in the art would not accept that SEQ ID NO:7 is likely to be an ion channel based on sequence similarity, by itself. See the Examiner's Answer, pages 3-4. We find it unnecessary to address this dispute because the claimed nucleic acids lack utility even assuming that they encode an ion channel protein.

[3] Appellants have cited a GenBank entry as evidence that SEQ ID NO:7 is a calcium channel protein. See the Appeal Brief, page 12. The cited reference, however, does not appear to represent the state of the art as of the effective filing date: the GenBank entry states that it was "[s]ubmitted (28-DEC-2000)" while this application has an apparent effective filing date of August 2, 2000. Nor can the post-filing evidence be considered to merely confirm a statement in the specification. The specification states that SEQ ID NO:7 "share[s] structural similarity with mammalian ion channel proteins, and particularly voltage-gated potassium channel proteins." Page 2 (emphasis added). Appellants have pointed to nothing in the specification that characterizes SEQ ID NO:7 as a calcium channel protein. Since utility is determined as of the filing date, see In re Brana, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995), and the GenBank entry represents a post-filing state of the art, it is not entitled to any weight in the determination of utility.

presently available benefit to the public. Cf. Fisher, 421 F.3d at 1371. Mere characterization as an ion channel also fails to provide a specific utility, because it does not "provide a well-defined and particular benefit to the public." Id.

Appellants also argue that "the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips" (Appeal Brief, page 16); that they are useful in mapping human chromosomes (id., page 18); and that they "are useful for functionally defining exon splice-junctions" (id.).

We find that none of these uses meet the requirements of § 101. In this case, as in Fisher, the generic uses asserted by Appellants – assessing gene expression, mapping human chromosomes, and defining exon splice-junctions – are neither substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 421 F.3d at 1373 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at 1374.

Finally, Appellants argue that the identified polymorphisms in SEQ ID NO:7 makes the nucleic acids useful in "forensic analysis." Appeal Brief, pages 5-11.

We do not agree that the disclosed polymorphisms establish the utility of the claimed nucleic acids. First, Appellants' argument lacks support in the specification or

in the evidence of record. The specification discloses the presence of nine polymorphisms in SEQ ID NO:7 (pages 15-16) but discloses no utilities based on detection of the polymorphism. In particular, the specification does not disclose that the polymorphisms are useful markers for forensic analysis.

In addition, the polymorphism-based utility is neither substantial nor specific. It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphisms, or any polymorphism for that matter, could achieve, but not one for which the claimed nucleic acids have been used in the real world. See Fisher, 421 F.3d at 1373. It is not specific because nothing about the asserted utility sets apart the polymorphisms in the claimed nucleic acids from any other polymorphism found in the human genome. See id. at 1374.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1 and 5-9.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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